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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,492	12/20/2004	Sachiko Kato	506.44566X00	5483

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EXAMINER

NOLAN, JASON MICHAEL

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 05/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/518,492

Applicant(s)

KATO ET AL.

Examiner

Jason M. Nolan, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/21/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-31 are currently pending in the instant application.

Information Disclosure Statement

Applicant's information disclosure statement (IDS), filed on March 21, 2005 has been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

Priority

Receipt is acknowledged of a certified copy of the Japan 2002-179616 (filed 06/20/2002) application referred to in the oath or declaration or in an application data sheet. If this copy is being filed to obtain the benefits of the foreign filing date under 35 U.S.C. §§ 119(a)-(d), applicant should also file a claim for such priority as required by 35 U.S.C. § 119(b). If the application being examined is an original application filed under 35 U.S.C. § 111(a) (other than a design application) on or after November 29, 2000, the claim for priority must be presented during the pendency of the application, and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior foreign application. See 37 CFR § 1.55(a)(1)(i). If the application being examined has entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the claim for priority must be made during the pendency of the application and within the time limit set forth in the PCT and Regulations of the PCT. See 37 CFR § 1.55(a)(1)(ii). Any claim for priority under 35 U.S.C. §§ 119(a)-(d) or (f) or 365(a) or (b) not presented within the time period set forth in 37 CFR § 1.55(a)(1) is considered to have been waived. If a claim for foreign priority is presented after the time period set forth in 37

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CFR § 1.55(a)(1), the claim may be accepted if the claim properly identifies the prior foreign application and is accompanied by a grantable petition to accept an unintentionally delayed claim for priority. See 37 CFR § 1.55(c). *Please amend the Specification so that the first paragraph includes the claim for foreign priority.*

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

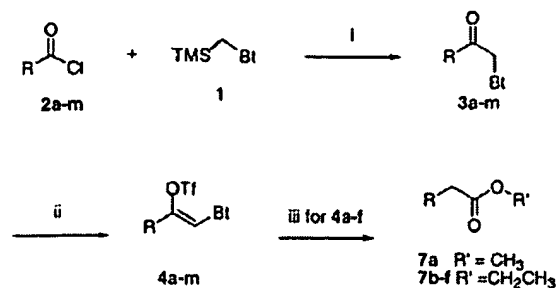
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 (Claims 5-9 and 11-17 depend from Claim 1) is drawn to a process of producing compounds of formula (IV) comprising the “reacting” of a carbonyl compound of formula (I) with an anhydride compound of formula (II) in the presence of a pyridine derivative (base) of formula (III).

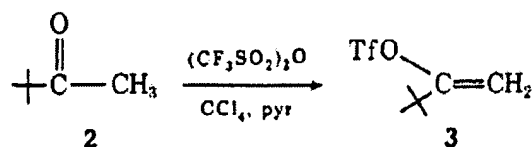
Claims 1, 5-8, and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Katritzky *et al.* (*J. Org. Chem.* **2001**, 66, 5606-5612 and *Org. Lett.* **2000**, 2(24), 3789-3791). Katritzky *et al.* teaches a process of reacting the compounds according to formulae 3a-m with Tf₂O (anhydride) and 2,6-lutidine (pyridyl base) in CH₂Cl₂ to arrive at compounds according to formulae 4a-m, shown below.

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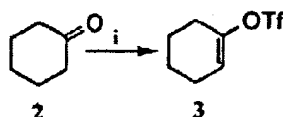


^a Reagents and conditions: (i) THF, reflux; (ii) Tf₂O, 2,6-lutidine, CH₂Cl₂, 0–20 °C; (iii) (a) NaOCH₃, acetonitrile, 65 °C, 2 h, (b) concentrated HCl in an alcohol, reflux.

Claims 1, 5-9, and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Stang *et al.* (*J. Org. Chem.* **1974**, 39(4), 581-582). **Claim 9** defines formula (III) as pyridine. Stang *et al.* teaches a process of reacting compound 2 with Tf₂O (anhydride) and pyridine (base) in CCl₄ to afford compound 3, shown below.



Claims 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Lai *et al.* **Claims 15-17** are drawn to the process of **Claim 1**, wherein the substituents of formula (I) are linked together such that the carbonyl moiety of the formula is part of a ring. Lai *et al.* teaches the sulfonation of cyclohexane using Tf₂O (anhydride) and Na₂CO₃ in CH₂Cl₂ to afford compound 3, shown below.



^a(i) Tf₂O, Na₂CO₃, CH₂Cl₂

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Included in the text, Lai discusses the use of sodium carbonate as the base that provided the optimal result, however, the use of 2,6-lutidine (pyridyl base) as the base worked on a kilogram scale, but was accompanied by by-products making purification more difficult (page 409-410). Nevertheless, the use of a pyridine derivative as a base for the sulfonation of a cyclo-carbonyl compound is discussed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. *Determining the scope and contents of the prior art.*
2. *Ascertaining the differences between the prior art and the claims at issue.*
3. *Resolving the level of ordinary skill in the pertinent art.*
4. *Considering objective evidence present in the application indicating obviousness or nonobviousness.*

Claims 2-4, 10, and 18-31 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Stang *et al.* (*Synthesis*, 1982, p106-107), taken alone.

Independent **Claims 2-4** are drawn to the process of producing compounds of formula (IV) comprising the preparation of a mixture of an anhydride compound of

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formula (II) and the a pyridine of formula (III) – **Claims 2-3**, or collectively formula (V) – **Claim 4**, followed by the addition of a compound of formula (I).

Determination of the scope and content of the prior art (MPEP § 2141.01)

In the review article published in 1980, Stang *et al.* teaches the various methods of producing vinyl perfluoroalkanesulfonic esters. More specifically, Stang discusses general procedures for sulfonating acyclic or cyclic carbonyl compounds, making note of the most commonly used bases (pyridine, lutidine, triethylamine, sodium carbonate, sodium hydrogen carbonate, and 2,6-di-*t*-butyl-4-methyl-pyridine) and solvents (dichloromethane, carbon tetrachloride, pentane, chloroform, and benzene), as well as insight on the mechanism. The role of the base in this chemistry is to absorb the acid produced in the reaction as well as to serve as a catalyst for enolization. If the base is an inorganic base (such as sodium carbonate), the reaction proceeds as a heterogeneous solution, as is found with some organic bases such as pyridine, lutidine, and triethylamine. The organic base will interact with the anhydride (formula (II)) to give amine salts that precipitate out of solution. Stang points out that the actual sulfonation (key bond forming step between oxygen and sulfur) is accomplished via the salts (formula V in Claim 3-4) and it was found that the use of organic bases leads to tars and purification difficulties. These issues lead to the use of 2,6-di-*t*-butyl-4-methylpyridine as the base, which was found to give a homogeneous solution because the base is too sterically hindered to react with the anhydride to form salts resulting in higher yields and a cleaner purification.

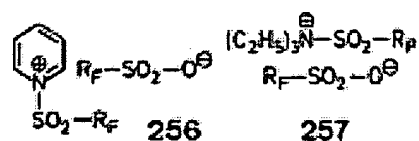
Ascertainment of the difference between the prior art and the claims (MPEP § 2141.02)

The review article is a broad teaching (review article), referenced in most documents in the IDS, STN reaction search report, and Specification. The article (as well as subsequent articles by Stang *et al.*, see IDS) teaches towards the use of 2,6-di-*t*-butyl-4-methylpyridine (in order to avoid the salt formation and purification difficulties), whereas the instant application teaches away from 2,6-di-*t*-butyl-4-methylpyridine (see proviso in claims) and towards the formation of the salts (formula V) in order to affect sulfonation.

The experimental procedure outlined by Stang *et al.* (Method G, p. 107) teaches the dissolution of the base and the carbonyl compound followed by the one-portion addition of the anhydride. The time before the addition of the anhydride is only the time needed to cool the reaction mixture to the desired temperature. The protocol outlined in Claims 2-4 in the instant application offers to prepare a mixture of formula V from the addition of the base (formula III) and the anhydride (formula II), before the addition of the carbonyl starting material (formula I). Therefore, the experimental difference is the order of addition between the substrate (carbonyl compound) and two reagents (base and anhydride).

Finding of prima facie obviousness--rational and motivation (MPEP § 2142-2413)

One skilled in the art would be motivated to improve the process to be more cost-efficient for large-scale synthesis (see Specification, page 3 and Lai *et al.* Syn. Comm. p. 410 (IDS)) and attempt the reaction using cheaper bases (formula III) than the commonly used 2,6-di-*t*-butyl-4-methyl-pyridine. The use of pyridine and 2,6-lutidine has worked to fulfill this need in the art, presented herein by Katritzky and Stang. Therefore, the key issue upon examination is the order of addition between the substrate (formula I) and the reagents (formulae II and III). **Claims 2-4** (and subsequent dependent claims) are drawn to a process comprising the addition of the substrate to a suspension of formulas II and III (Claims 2-3) or formula V (Claim 4). As pointed out on page 107 by Stang "the actual sulfonation is accomplished by **256** or **257** rather than the anhydride itself," shown here.

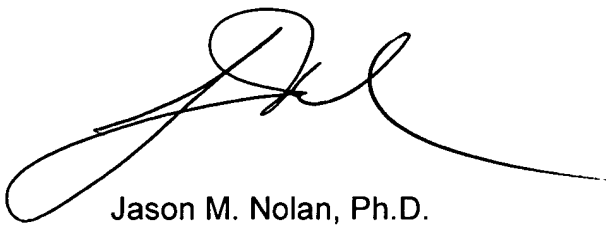


One skilled in the art would thus be motivated to utilize the processes as taught by Stang using a pyridyl base other than 2,6-di-*t*-butyl-4-methyl-pyridine in order to form the salt, but vary the order of addition, between reagents and substrate in order to have a higher concentration of the salts **256** and **257** and arrive at the instantly claimed process with the expectation of success via an optimized, known process. Absent factual unexpected, unobvious, and beneficial results, the claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art, providing a cheaper process.

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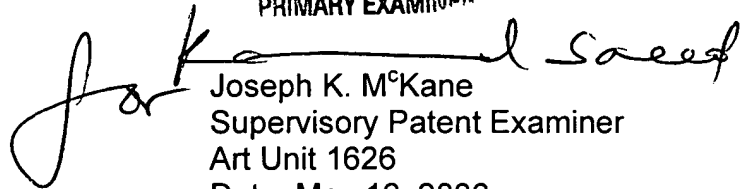
Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jason M. Nolan, Ph.D.** whose telephone number is **(571) 272-4356** and electronic mail is **Jason.Nolan@uspto.gov**. The examiner can normally be reached on Mon - Fri (9:00 - 5:30PM). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph M^cKane** can be reached on **(571) 272-0699**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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KAMALA A. SAEED, PH.D.
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Joseph K. M^cKane
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Art Unit 1626
Date: May 16, 2006